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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,763	04/24/2001	Richard C. Willson III	009MUS	6416

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EXAMINER	
FREDMAN, JEFFREY NORMAN	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/841,763	Applicant(s) WILLSON ET AL.	
	Examiner Jeffrey Fredman	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2004* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-43,45,49,51,52,54-57 and 59-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-43, 45, 49, 51, 52, 54-57, 59-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The rejection of claims 44, 48, 51, 54 under 35 U.S.C. 112, second paragraph, are withdrawn in view of the amendment.

1. Claims 54 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 54 appears to be a dependent claim, reciting the phrase "A composition of Claim", but no claim number follows. It is therefore entirely indefinite what are the metes and bounds of claim 54.

In claim 62, the phrase "of sufficiently low ionic strength that the DNA is substantially insoluble" is vague and indefinite because no specific ionic strength is provided. As MPEP 2173.02 notes " If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112, second paragraph would be appropriate." Here, the claim reads on a mixture of DNA and a compaction agent, but there is no way to know whether one is infringing because it is unclear what level of insolubility is required and no ionic strength is given. If 50% of the DNA is insoluble, would there be infringement? How about 10% or 75%? Given the absence of any clearcut metes and bounds in this claim, it is vague and indefinite what is meant by the phrase "of sufficiently low ionic strength that the DNA is substantially

insoluble." The prior art of Moradpour will be applied since the DNA is contained in a liposome, which is not a soluble DNA.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 39, 40, 41, 43, 45, 49, 51, 52, 55-57, 60-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Moradpour et al (Biochem. Biophys. Res. Comm. (1996) 221:82-88) as evidenced by Davis et al (Biotechniques (1996) 21(1):92-99).

Moradpour teaches a composition which comprises double CsCl banded DNA (see page 83, subheading "plasmid constructs") which is mixed with cholesteryl-spermidine (see page 83, subheading "transfection experiments") and MEM (see page 83).

With regard to claims 40, 43, 45, 56 and 57, Davis evidences that CsCl double banded DNA is free of RNAse, protein contamination and endotoxin as discussed above. Therefore, the double CsCl banded DNA of Moradpour inherently meets the requirements of claims 40, 43-46 and 56-58.

With regard to claim 41, any DNA may encode a protein that could be vaccinated into mice and therefore the nucleic acid of Moradpour, which expresses galactosidase, would meet this limitation.

With regard to claims 39, 49, 51, 52 and 55, Moradpour expressly teaches a composition in which the double CsCl banded DNA is mixed with spermidine, which is a polyamine that is expressly listed in the claims (see page 83, subheading "transfection experiments").

With regard to claims 39, and 60-62, Moradpour teaches mixing the solution with Eagle's MEM, which is composed, in part, of KCl and NaCl.

4. Claims 39, 40, 43, 45, 49, 51, 52, 54-57, 59-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Arscott et al (Biopolymers (1995) 36(3):345-364) as evidenced by Davis et al (Biotechniques (1996) 21(1):92-99).

Arscott teaches a composition comprising DNA (see page 347, column 2, subheading "DNA") which is mixed with NaCl, with Hexammine cobalt (see page 348, column 1, subheading "DNA condensation procedure"), and with ethanol (see table 1 and page 348, column 1, subheading "alcoholic buffers").

With regard to claims 40, 43, 45, 56 and 57, Davis evidences that CsCl double banded DNA is free of RNAse, protein contamination and endotoxin as discussed above. Arscott cites the standard laboratory manual, Sambrook, for the DNA preparation method and Sambrook teaches DNA purification using the double CsCl banded method which therefore inherently meets the requirements of claims 40, 43, 45, 56 and 57.

With regard to claim 63, the stock solution used by Arscott comprises EDTA (see page 347, column 1, subheading "DNA") which solution is the solution mixed with the NaCl, Hexammine cobalt and ethanol (see page 348, column 1).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moradpour et al (Biochem. Biophys. Res. Comm. (1996) 221:82-88) in view of Webster et al (Vaccine (1994) 12(8)1495-1498).

Moradpour teaches a composition which comprises double CsCl banded DNA (see page 83, subheading "plasmid constructs") which is mixed with cholesteryl-spermidine (see page 83, subheading "transfection experiments") and MEM (see page 83).

With regard to claims 40, 43, 45, 56 and 57, Davis evidences that CsCl double banded DNA is free of RNAse, protein contamination and endotoxin as discussed

above. Therefore, the double CsCl banded DNA of Moradpour inherently meets the requirements of claims 40, 43-46 and 56-58.

With regard to claim 41, any DNA may encode a protein that could be vaccinated into mice and therefore the nucleic acid of Moradpour, which expresses galactosidase, would meet this limitation.

With regard to claims 39, 49, 51, 52 and 55, Moradpour expressly teaches a composition in which the double CsCl banded DNA is mixed with spermidine, which is a polyamine that is expressly listed in the claims (see page 83, subheading "transfection experiments").

With regard to claims 39, and 60-62, Moradpour teaches mixing the solution with Eagle's MEM, which is composed, in part, of KCl and NaCl.

Moradpour does not teach use of influenza proteins in liposomal construct.

Webster teaches double CsCl banded DNA, specifically of vectors with influenza proteins for use as a vaccine (see page 1495, column 2, subheading "DNA vaccines").

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the liposome of Moradpour with the vaccine vector of Webster since Moradpour notes "Cholesteryl-spermidine (Transfectal) represents a novel cationic compound for efficient transfection of cultured cells in vitro and has the potential to be used for gene transfer in vivo (see abstract)." So Moradpour expressly suggests formation of the composition for gene transfer in vivo, which includes situations such as vaccination, and Webster teaches that DNA vaccines which express influenza proteins are useful, so it would have been obvious to transfer the vector of

Webster using the system of Moradpour in order to efficiently place the nucleic acid in cells to obtain high efficiency protection by inducing high levels of protein expression.

Response to Arguments

8. Applicant's arguments filed February 2, 2004 have been fully considered but they are not persuasive.

With regard to the first two 102 rejections, Applicant's amendment has overcome these rejections. However, Moradpour meets the requirements of this product claim. Applicant's entire argument involves the fact that Moradpour is not purifying DNA. This is entirely correct. It is also entirely irrelevant. Since Moradpour teaches a composition which is structurally identical to that of Applicant's, Moradpour properly anticipates the claims to which it is applied. This rejection is therefore maintained.

The other rejections are new and necessitated by Applicant's amendment.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman
Primary Examiner
Art Unit 1634